

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION,

Plaintiff,

V.

SANDOZ INC.,

Defendant.

))))))))))

C.A. No.: 09-cv-1750-JFM

**DEFENDANT SANDOZ INC.’S BRIEF IN OPPOSITION
TO PLAINTIFF’S MOTION TO DISMISS
COUNTS III AND IV OF DEFENDANT’S COUNTERCLAIM**

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I. INTRODUCTION

This suit relates to two patents: U.S. Patent No. 6,773,780 (“’780 patent”) and U.S. Patent No. 5,667,775 (“’775 patent”). Sandoz Inc. (“Sandoz”) brought declaratory judgment counts against the ’780 patent to protect its right, as authorized by the Hatch-Waxman Act,¹ to bring to market the first generic version of sevelamer hydrochloride. Sandoz has the potential to bring its drug product to market as early as August 2013, over a year before the ’775 patent expires in September 2014. The Court should not allow Plaintiff Genzyme Corporation (“Genzyme”) to deny Sandoz’s right and thus limit competition in the generic marketplace contrary to the goals of the Hatch-Waxman Act.

Genzyme has caused this controversy by: (1) listing both the ’780 and ’775 patents in the FDA’s Orange Book;² (2) declining to seek resolution of the ’780 patent but suing Sandoz on the ’775 patent; (3) refusing a consent judgment that Sandoz does not infringe the ’780 patent; and (4) instead, unilaterally granting a covenant not to sue (“CNS”) to Sandoz on the ’780 patent. By these actions, Genzyme seeks to foreclose Sandoz from challenging the ’780 patent and keeping alive its right to bring its drug product to the market as early as possible.

Sandoz attempted to negotiate a consent decree or settlement order to remove all harm,³ but Genzyme refused, claiming its CNS resolved the dispute. Sandoz thus asserts Counts III and IV to

¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”).

² The FDA’s publication, “*Approved Drug Products with Therapeutic Equivalence Evaluations*,” is commonly known as the Orange Book and is available online at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

³ The Hatch-Waxman Act authorizes the use of a consent decree or settlement order to remove the harm (i.e., to allow FDA approval of its ANDA) caused by Orange Book-listed patents that the parties do not

obtain an order from this Court finding that the '780 patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). That order will not only protect Sandoz's right to compete, but it also will set a bar to prevent Endo from delaying the first sale of its product by establishing a definite date relevant to a "Failure to Market" forfeiture of the 180-day exclusivity claimed by Endo. *See* § 355(j)(5)(D)(i)(I).

Genzyme's actions have created real and immediate harm to Sandoz in accord with the *MedImmune* "all-the-circumstances" test. Its resolution by the Court now is consistent with the policy of the Hatch-Waxman Act, which is to advance timely market entry of generic pharmaceuticals through resolution of challenged patents that are listed in the Orange Book. Sandoz thus opposes Genzyme's motion pursuant to Fed. R. Civ. P. 12(b)(1) and requests the Court maintain Sandoz's Counterclaim Counts III and IV, which allege that the '780 patent is not infringed and is invalid.

II. SUMMARY OF ARGUMENT

Genzyme is harming Sandoz by using the '780 patent to exclude Sandoz from the marketplace for sevelamer hydrochloride and preventing Sandoz from challenging the '780 patent in court. Sandoz has the potential to enter the market before the first ANDA applicant, Endo. By refusing to litigate the merits of the '780 patent or enter into a consent decree or settlement order that Sandoz is not liable for infringing the '780 patent, Genzyme wrongly attempts to limit generic competition for Renagel[®] to Genzyme and Endo and deprive the public of the benefits of the Hatch-Waxman Act for up to one year. Such activity creates a dispute between the parties. Genzyme's refusal to enter into a consent decree or settlement order alone belies the real existence of the parties' dispute. By preventing Sandoz from

dispute are in issue in the lawsuit. *See* 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(BB). The statute, however, does not provide for the same relief when the patentee offers a covenant not to sue. *Id.*

entering the market, Genzyme's action will result in lost profits to Sandoz. Hence, the all-the-circumstances test requires a finding that declaratory judgment jurisdiction exists.

III. STATEMENT OF FACTS

A. ANDA Background

When Genzyme filed its New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval for its drug product Renagel[®], it listed six patents in the Orange Book, including the '780 patent and the '775. *See* § 355(b)(1). Notably, the '780 patent is the last to expire of the patents listed in the Orange Book for Renagel[®], expiring on October 18, 2020.

By listing these patents in the Orange Book, Genzyme averred that they claim sevelamer hydrochloride, the active pharmaceutical ingredient ("API") of Renagel[®], or a method of using sevelamer hydrochloride. *See id.*

| Appl No | Prod No | Patent No | Patent Expiration | Drug Substance Claim | Drug Product Claim | Patent Use Code | Delist Requested |
|------------------------|---------|-----------|-------------------|----------------------|--------------------|-----------------------|------------------|
| 021179 | 001 | 5496545 | Aug 11, 2013 | | | U-246 | |
| 021179 | 001 | 5667775 | Sep 16, 2014 | | | U-246 | |
| 021179 | 001 | 6509013 | Aug 11, 2013 | | | | |
| 021179 | 001 | 6733780 | Oct 18, 2020 | | Y | | |
| 021179 | 001 | 7014846 | Aug 11, 2013 | | Y | U-246 | |
| 021179 | 001 | 7459151 | Aug 11, 2013 | | | U-246 | |

When a generic pharmaceutical seeks approval to market a generic version of a particular drug, it must file an Abbreviated New Drug Application ("ANDA"), and within the ANDA the generic pharmaceutical must file a certification for each patent listed in the Orange Book for that drug. *See* § 355 (j)(2)(A)(vii). The generic pharmaceutical must certify that either:

- I. no patent has been filed with the FDA;

- II. the listed patent has expired;
- III. FDA approval should be delayed until the expiration of the listed patent; or
- IV. the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.

See § 355(j)(2)(A)(vii)(I)–(IV). These certifications are known as paragraph I, II, III, and IV certifications, respectively. Submission of an ANDA that contains a paragraph IV certification constitutes an artificial act of infringement upon which a lawsuit may be filed. *See* 35 U.S.C. § 271(e)(2)(A); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). If a generic pharmaceutical files a paragraph IV certification, it must notify the NDA-holder, also known as the brand manufacturer of the drug. § 355(j)(2)(B). The FDA may immediately approve an ANDA that contains a paragraph IV certification unless the brand manufacturer sues the ANDA applicant within forty-five days after receiving notice of the paragraph IV certification. § 355(j)(5)(B). Upon such suit, the FDA will not approve the ANDA until thirty months after the brand manufacturer received notice.⁴ § 355(j)(5)(B)(iii). Without approval of the ANDA, the generic pharmaceutical may not market the generic version of the drug.

To incentivize generic pharmaceuticals to file ANDAs and thereby increase the volume of generic drugs on the market, the Hatch-Waxman Act grants 180 days of market exclusivity to the first generic pharmaceutical to file (“first applicant”) a paragraph IV certification for a particular drug. § 355(j)(5)(B)(iv). Exclusivity is awarded on each drug based on the patent or patents challenged through a paragraph IV certification. *Id.*

A first applicant will forfeit its 180-day exclusivity period under the following provisions: (1) the first applicant fails to market its generic drug, § 355(j)(5)(D)(i)(I); (2) the first applicant withdraws

⁴ If, before the thirty months expire, a court finds the patent invalid or not infringed, or the court enters a settlement order or consent decree to the same effect, then the FDA may approve the ANDA before the termination of the thirty-month period. § 355(j)(5)(B)(iii)(I).

its ANDA application, § 355(j)(5)(D)(i)(II); (3) the first applicant withdraws or amends its paragraph IV certification on the patent(s) on which exclusivity is based, § 355(j)(5)(D)(i)(III); (4) the first applicant fails to obtain tentative approval of its ANDA by the FDA within 30 months of filing its ANDA, § 355(j)(5)(D)(i)(IV); (5) a court makes a final decision—from which no appeal has been or can be taken—that the first applicant entered into an agreement with the NDA-holder or another ANDA-filer that violates antitrust laws, § 355(j)(5)(D)(i)(V); or (6) all of the patents that formed the basis of exclusivity have expired, § 355(j)(5)(D)(i)(VI).

This declaratory judgment claim pertains to Sandoz's right to attempt to bring to market a generic version of Renagel[®], sevelamer hydrochloride, as quickly as the Hatch-Waxman Act permits. Sandoz asserts Counts III and IV in order to maintain its right to obtain an order from this court finding that the '780 patent, upon which Endo's asserted exclusivity is based, is invalid or not infringed. *See* § 355(j)(5)(D)(i)(I)(bb)(AA).

Under the Failure to Market provision, if seventy-five days have passed since the FDA approved the first applicant's ANDA or thirty months have passed since the first applicant submitted its ANDA, the first applicant has seventy-five days to begin marketing its product or it will forfeit any 180-day exclusivity if: (1) a court finds the patent(s) on which exclusivity is based to be invalid or not infringed, and no appeal has been or can be taken; (2) a court enters a consent decree or settlement order that the patent(s) on which exclusivity is based is invalid or not infringed; or (3) the brand manufacturer withdraws from the Orange Book the patent(s) on which exclusivity is based. § 355(j)(5)(D)(i)(I)(aa), (bb). Because the statute relies on "the later of" the events listed, should none of these three events occur with regard to the patent or patents on which exclusivity is based, the first applicant may delay from marketing its generic product almost indefinitely—up until the expiration date of the patent or

patents. *See id.* Cf. *Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42, 48 (D.D.C. 2009) (discussing failure to market provision). This is known as exclusivity “parking.”⁵

The Hatch-Waxman Act also contains a provision titled “civil action to obtain patent certainty,” which establishes jurisdiction for a generic pharmaceutical to bring a declaratory judgment claim against any patent on which it files a paragraph IV certification. *See* § 355(j)(5)(C); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007) (“*Teva*”). Section 355(j)(5)(C)(i)(II) authorizes a generic manufacturer to bring a noninfringement declaratory judgment claim if (1) it files a notice of the paragraph IV certification along with an offer of confidential access pursuant to § 355(j)(5)(C)(i)(cc)(III) and a detailed statement of the bases for invalidity and noninfringement of the patent pursuant to § 355(j)(2)(B)(iv), and (2) the brand manufacturer does not assert an infringement claim against the generic for infringement of the patent that was the subject of the paragraph IV certification within a forty-five day period. An invalidity declaratory judgment counterclaim may be brought without the offer of confidential access. *See* § 355(j)(5)(C)(i)(I)(cc).

B. This ANDA Litigation

Sandoz filed ANDA No. 91-255 with the FDA for approval of its generic sevelamer hydrochloride drug product, and notified Genzyme pursuant to § 355(j)(2)(B) that it had filed paragraph IV certifications on the ’775 patent and the ’780 patent.⁶ Sandoz’s notice included an offer of confidential access and a detailed statement of the bases for invalidity and noninfringement of the ’775 and ’780 patents. (*See* Ex. 2, Letter from Edmund J. Haughey, authorized agent for Genzyme, to Jean

⁵ (Ex. 1, FDA Letter from Gary J. Buehler, Director of the Office of Generic Drugs, to Marc A. Goshko, Executive Director of Teva North America (Jan. 17, 2008), at n.5–6, *available at* <http://www.fda.gov/ohrms/dockets/DOCKETS/07n0389/07n-0389-let0003.pdf> (FDA recognition that exclusivity parking is still available under the MMA)).

⁶ Sandoz also filed paragraph III certifications on the four listed patents that expire on August 11, 2013.

Domenico, Manager of Regulatory Affairs for Sandoz (May 21, 2009) (confirming receipt of notice and offer of confidential access)). Genzyme filed suit within the forty-five day period, but only alleged infringement of the '775 patent. (Ex. 3, Compl., Dkt. No. 1, at 3–4). When Genzyme failed to bring suit against Sandoz for infringement of the '780 patent, the Hatch-Waxman statute authorized Sandoz to file a declaratory civil action to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5).

C. The First Endo ANDA Certification

On information and belief, Endo Pharmaceuticals Inc. (“Endo”) originally filed on May 22, 2008 a paragraph IV certification challenging the '780 patent. Genzyme did not sue Endo for infringement of the '780 patent and Endo did not file a declaratory judgment claim as the statute authorized. Endo thus alleges that it has obtained the right to 180 days of exclusivity based solely on the '780 patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv); (Ex. 4, Endo’s Mem. Supp. Mot. Dismiss, Dkt. No. 48, at 2–3).

D. The Lupin ANDA Litigation

On about January 20, 2009, Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, “Lupin”) notified Genzyme that it had filed an ANDA for Renagel[®] tablets and had made paragraph IV certifications for, *inter alia*, the '780 and '775 patents. *See Genzyme Corp. v. Lupin Ltd.*, No. 09-00563-JFM (D. Md. filed Mar. 6, 2009) (Ex. 5, Compl., Dkt. No. 1, at ¶ 20). Genzyme sued Lupin in this Court for infringement of the '775 patent but did not sue Lupin under the '780 patent. *Id.*; (Ex. 5, at ¶¶ 19–26). Lupin answered, *inter alia*, with a counterclaim for declaratory judgment that it did not infringe the '780 patent. *Id.*; (Ex. 6, Ans. & Countercl., Dkt. No. 31, at ¶¶ 41–44). Genzyme thereafter granted a CNS to Lupin, and Lupin then withdrew its counterclaim against the '780 patent. *See id.*; (Ex. 7, Dkt. No. 44) (voluntarily dismissing with prejudice Count VII of Counterclaim).

E. The Impax ANDA Litigation

On about January 27, 2009, Impax Laboratories Inc. (“Impax”) notified Genzyme that it had filed an ANDA for Renagel[®] tablets and had made paragraph IV certifications for the ’780 and ’775 patents. *See Genzyme Corp. v. Impax Labs., Inc.*, No. 09-00653-JFM (D. Md. filed Mar. 13, 2009); (Ex. 8, Compl., Dkt. No. 1, at ¶ 13). In this Court, Genzyme sued Impax for infringement of the ’775 patent but did not sue Impax under the ’780 patent. *Id.*; (Ex. 8, at ¶¶ 12–17). Impax answered, *inter alia*, with a counterclaim for declaratory judgment that it does not infringe the ’780 patent. *Id.*; (Ex. 9, Ans. & Countercl., Dkt. No. 29, at ¶¶ 52–56). Genzyme thereafter granted a CNS to Impax and moved to dismiss Impax’s counterclaim against the ’780 patent. *Id.*; (Ex. 10, Genzyme’s Mem. Supp. Mot. Dismiss, Dkt. No. 45). Impax then withdrew its counterclaim counts against the ’780 patent. *Id.*; (Ex. 11, Dkt. No. 55) (voluntarily dismissing without prejudice Counts III and IV of Counterclaim).

F. The Second Endo ANDA Certification

It was not until other generics had challenged the earlier-expiring ’775 patent, and Genzyme had sued those generics, that Endo filed a paragraph IV certification on the ’775 patent. Thus, on about August 18, 2009, Endo notified Genzyme that it had amended its paragraph III certification on the ’775 patent to a paragraph IV certification. *Genzyme Corp. v. Endo Pharms. Inc.*, No. 09-02589-JFM (D. Md. filed Oct. 1, 2009) (Ex. 12, Compl., Dkt. No. 1, ¶¶ 13–14). In its suit against Endo in this Court, Genzyme asserts that Endo infringes only the ’775 patent and still makes no claim against Endo based on the ’780 patent. *See id.*; (Ex. 12, at ¶¶ 12–18). Moreover, neither Genzyme nor Endo, in their papers filed with the Court, state whether Genzyme has granted a CNS to Endo on the ’780 patent.

G. Harm to Sandoz

Genzyme also has refused to grant a consent decree or settlement order to Sandoz on the ’780 patent. Sandoz requested a consent decree on about October 15, 2009 and November 18, 2009 (Ex. 13,

Letter from Thomas Filarski, Counsel for Sandoz, to Brian O'Reilly, Counsel for Genzyme (Dec. 18, 2009)), but Genzyme has refused. (Ex. 14, Letter from Brian O'Reilly to Thomas Filarski (Dec. 21, 2009)). A CNS does not have the same effect as a consent decree because it does not affect the FDA's ability to approve Sandoz's ANDA. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1296–97 (Fed. Cir. 2008) *cert. denied*, 129 S. Ct. 1316 (2009).

Sandoz is the only defendant who can challenge this patent. Genzyme's actions with respect to Lupin and Impax foreclose a Failure to Market forfeiture from occurring in those cases by way of a consent decree or court decision that the '780 patent is not infringed, is invalid, or is not enforceable. *See* § 355(j)(5)(D)(i)(I).

Should the Court dismiss Sandoz's counterclaim counts against the '780 patent, no event will occur under the Failure to Market provision § 355(j)(5)(D)(i)(I)(bb) to allow market entry of multiple generic sevelamer hydrochloride drug products prior to 2020, the expiration of the '780 patent. Genzyme did not assert the '780 patent against any defendant and, as already noted, Lupin and Impax voluntarily dismissed their declaratory judgment counterclaim counts against the '780 patent.⁷ No other litigation involving the Renagel[®] product and the '780 patent is pending.⁸ Unless the Court allows Sandoz to maintain its Counts III and IV against the '780 patent, no one will be able to litigate the questions of infringement or validity of the '780 patent. Under such circumstances, the FDA has held that the Failure to Market provision does not apply and it will be impossible to trigger a forfeiture of

⁷ It appears that Genzyme offered to Lupin and Impax—and later unilaterally granted—a CNS on the '780 patent, just as it did for Sandoz.

⁸ Genzyme also sued Lupin and Impax on the '775 patent due to their ANDAs pertaining to a different drug product, Renvela[®]. *See Genzyme Corp. v. Lupin Ltd.*, No. 09-01258-JFM (D. Md. filed May 14, 2009); *Genzyme Corp. v. Impax Labs., Inc.*, No. 09-00846-JFM (D. Md. filed Apr. 3, 2009).

Endo's exclusivity. (Ex. 1, at n.5–6). This is true regardless of the outcome of Genzyme's suit against Endo on the '775 patent. Thus, Endo may delay entering the market up until the day before the expiration of the '780 patent, October 18, 2020. The MMA⁹ was designed to prevent such exclusivity parking. *See Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 357 (D. Del. 2009) (“[MMA] provisions are designed to . . . curb ‘parking’ of the exclusivity period.”).

IV. ARGUMENT

A. A Conflict Exists Between Genzyme And Sandoz Creating Declaratory Judgment Jurisdiction Because Genzyme Is Using The '780 Patent To Exclude Competitors From The Market, And Sandoz Is The Only Party Positioned To Challenge Genzyme In Court

Genzyme started this dispute when it first listed the '780 patent in the Orange Book. By doing so, Genzyme notified the generic industry that the '780 patent covers Renagel[®], thus putting up that patent for challenge by an ANDA applicant. Relying upon its biased view of the “intended result of the Hatch-Waxman Act,” (Pl.'s Br. at 9), however, Genzyme now wrongly seeks to avoid this challenge by Sandoz in order to protect its market for Renagel[®] as that drug heads for generic competition. By attempting to deny Sandoz a final determination on the '780 patent, Genzyme is barring Sandoz from its right to challenge an Orange Book-listed patent that is blocking FDA approval of its ANDA. Consequently, Genzyme is impeding Sandoz's ability to bring the first generic version of Renagel[®] to the market. Genzyme's actions are designed to create a bottleneck of subsequent-applicants,¹⁰ such as Sandoz, who cannot enter the market with generic Renagel[®] until after Endo's market entry, thus limiting competition. Should this Court deny declaratory judgment jurisdiction of the '780 patent,

⁹ Congress amended the Hatch-Waxman Act in 2003 with the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”). *See supra* note 1.

¹⁰ ANDA applicants who file paragraph IV certifications after the first applicant.

Genzyme will have prevented Sandoz from potentially entering the market in 2013, regardless of whether the Orange Book-listed '780 and '775 patents are invalid or not infringed.

Genzyme's actions are contrary to the intended result of the Hatch-Waxman Act. *See Teva*, 482 F.3d at 1344 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)) (chastising brand manufacturer for frustrating a central purpose of the Hatch-Waxman statute, which is "to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.") (alteration in original). Congress carefully promulgated the Hatch-Waxman Act to incentivize both the development of new drugs and the production of low cost generic alternatives for the public well-being. *See id.* Genzyme's improper "gaming" of the system should not be tolerated.

1. *MedImmune's All-The-Circumstances Test Requires A Finding That Declaratory Judgment Jurisdiction Exists*

By obtaining a judgment on the '780 patent, Sandoz has the potential to be the first generic pharmaceutical to bring a sevelamer hydrochloride product to the market. Therefore, under the all-the-circumstances test, jurisdiction exists for Sandoz's declaratory judgment counterclaim counts on the '780 patent. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) ("the question [for whether declaratory judgment jurisdiction exists] is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.") (citation omitted). The Federal Circuit first applied the Supreme Court's ruling in *MedImmune* to a Hatch-Waxman case in *Teva*. *See Teva*, 482 F.3d at 1336–40 (citing *MedImmune*, 549 U.S. 118).

In *Teva*, the Federal Circuit held that declaratory judgment jurisdiction exists for a generic pharmaceutical's counterclaim on any paragraph IV certified patent where: (1) the brand manufacturer lists patents in the Orange Book; (2) the ANDA contains paragraph IV certifications; and (3) the brand

manufacturer sues the generic pharmaceutical on one or more of the patents for which the generic pharmaceutical filed paragraph IV certifications. *Id.* at 1344.¹¹ The court’s decision coincided with what it found to be “[a] central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment”: “to enable competitors to bring cheaper, generic drugs . . . to market as quickly as possible.” *Id.* (alteration in original).

There is no question here that (1) Genzyme has listed six patents in the Orange Book for Renagel[®], including the ’780 patent; (2) Sandoz’s ANDA contains a paragraph IV certifications against the ’780 and ’775 patents; and (3) Genzyme sued Sandoz on only one of the patents for which Sandoz filed paragraph IV certification in its ANDA, i.e., the ’755 patent. Hence, *Teva* supports declaratory jurisdiction in this case. *Id.*

More recently, the Federal Circuit found declaratory judgment jurisdiction under the all-the-circumstances test where the *Teva* factors were met, but where a brand manufacturer went one step further to avoid litigation by unilaterally granting a CNS to the generic defendant. *See Caraco*, 527 F.3d at 1288, 1291. The court ultimately concluded that a unilateral CNS does not divest a court of jurisdiction where the generic defendant has the potential to be the first to market and the declaratory judgment claim relates to a patent that is blocking FDA approval of the generic pharmaceutical’s ANDA:

[I]n the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval. Moreover, an NDA holder’s

¹¹ The court reiterated that a claimant has the burden to prove that jurisdiction exists by showing that, when “all the circumstances” are considered, an Article III controversy exists. *Id.* at 1338. The court further noted that the claimant must meet three prongs under the all-the-circumstances test: (1) it has standing—including having an injury-in-fact that is both traceable to the other party and redressible by a favorable judgment, (2) the issue is ripe, and (3) the issue not rendered moot at any stage. *Teva*, 482 F.3d at 1337–38. Genzyme’s memorandum concedes all but the injury-in-fact component of standing. (Pl.’s Br. at 8–16). Sandoz responds accordingly.

covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA. . . . [W]here the first Paragraph IV ANDA filer fails to trigger its own exclusivity period, a subsequent Paragraph IV ANDA filer can only obtain FDA approval before the relevant Orange-Book-listed patents expire by obtaining a judgment that those patents are invalid or not infringed. . . . Under these circumstances, **even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'**

Id. at 1296–97 (quoting *MedImmune*, 549 U.S. at 127) (emphasis added); *see also* 1296 n.14. Therefore, the Federal Circuit reversed the district court's dismissal of the declaratory judgment count. *Id.* at 1297.

In *Caraco*, the patentee successfully sued the first applicant, Ivax, on only one of two Orange Book-listed patents, resulting in a judgment of patent validity and infringement. *Id.* at 1286. Caraco, the second applicant, filed paragraph IV certifications for both listed patents but the patentee only filed suit on the lone patent that it had successfully asserted against Ivax. *Id.* at 1288. In response to a declaratory judgment counterclaim against the unasserted patent, the patentee unilaterally granted Caraco a CNS and successfully moved to dismiss the counterclaim. *Id.* at 1288–89. The Federal Circuit reversed, however, holding that a controversy existed—even in view of a CNS—because only a judgment on the merits or a consent decree regarding the unasserted patent would remove the FDA approval-blocking injury caused by the patentee to the second applicant. *Id.* at 1296–97.

The first applicant could not launch until 2012 because of its loss on the '712 patent, one of the Orange Book-listed patents, which expires in that year. *Id.* at 1287. If Caraco won its case on both patents, it had the potential to enter the market before 2012, were the first applicant's 180-day exclusivity period not blocking it. *Id.* at 1296 n.14 (“the injury upon which Caraco's suit is premised is the delay (in triggering Ivax's exclusivity period) between now and when the '712 patent expires in 2012, not any delay (in triggering Ivax's exclusivity period) after the '712 patent expires.”). Therefore,

the court permitted Caraco to proceed on its counterclaim in order to trigger potentially the forfeiture of the first applicant's exclusivity period. *Id.* at 1296 ("Such a judgment is required to trigger the first Paragraph IV ANDA filer's exclusivity period and thus allow the FDA to approve the subsequent Paragraph IV ANDA").

Significantly, the Federal Circuit noted that costly litigation may be avoided and a subsequent-applicant's harm may be alleviated if the brand manufacturer grants a consent decree. *Id.* at 1293 n.11 ("it appears that if [the brand manufacturer] would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the [patent that was the subject of the declaratory judgment], such a decree would redress Caraco's alleged injury-in-fact"). The holding of *Caraco* thus establishes that, when patentees sue on less than all of the listed patents and use a CNS instead of the statutorily recognized settlement order or consent decree in resolving disputes, jurisdiction still exists for defendants to join other listed patents. *Id.* at 1285–86, 1293 n.11, 1297. This is exactly what has occurred here.

Declaratory judgment jurisdiction exists in this case because Sandoz has the ability to challenge the '780 patent under the Hatch-Waxman Act and the potential to be the first to enter the market for generic Renagel[®]. Sandoz is the only generic company to challenging both the '775 and '780 patents, the remaining two patents listed by Genzyme in the Orange Book that are blocking generic entry after August 11, 2013.¹² A Sandoz win on either noninfringement or invalidity of the '780 patent paves the way for Sandoz to be the first to enter market, because it sets a date that could ultimately cause a forfeiture of Endo's 180-day exclusivity period.

¹² Sandoz, Lupin, Impax, and Endo all have filed paragraph III certifications on the four patents that expire in 2013. Therefore, none may obtain FDA approval prior to the expiration date of those patents, August 11, 2013.

To deny Sandoz its ability to challenge the '780 patent and the potential to enter the market early, Genzyme sued Sandoz for infringement on only the '775 patent, and offered a CNS on the '780 patent after it had studied Sandoz's proposed ANDA drug product and must have concluded that Sandoz does not infringe the '780 patent. The Court should not allow Genzyme's improper attempt to control the generic Renagel[®] market. Genzyme could have prevented the harm to Sandoz if it had followed the Federal Circuit's guidance in *Caraco* and granted Sandoz's request for a consent decree. *See Caraco*, 527 F.3d at 1293 n.11.

That Genzyme granted Sandoz a unilateral CNS on the '780 patent does not divest this Court of jurisdiction. Genzyme's CNS does not moot the issue because the '780 patent is still listed in the Orange Book and will prevent FDA approval of Sandoz's ANDA. *See Caraco*, 527 F.3d at 1295–96. Under these circumstances, “there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Caraco*, 527 F.3d at 1288 (Fed. Cir. 2008) (citing *MedImmune*, 549 U.S. at 127) (citation omitted)).

Genzyme, however, misdirects the Court to inapplicable standards and cases. For example, paying only lip-service to *MedImmune*'s all-the-circumstances test, Genzyme instead focuses improperly on narrow concepts from the overruled “reasonable apprehension of suit” test. (Pl.'s Br. at 1.A). Reasonable apprehension of suit is no longer the test for standing, nor is it the harm that Sandoz faces. *See Caraco*, 527 F.3d at 1297 (“This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because [the brand manufacturer's] actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market.”). *MedImmune*'s all-the-circumstances test was intended to broaden the court's declaratory judgment jurisprudence to the extent permissible under Article III. *Teva*, 482 F.3d at 1338. Genzyme, moreover,

asks the Court to consider outdated, tangential, and inapposite non-Hatch-Waxman decisions. (Pl.’s Br. at 8 & n.5). But, none of this precedent negates the binding precedent of *Teva* and *Caraco*, which support Sandoz’s injury-in-fact.

2. *Janssen* Is In Accord With Other Federal Circuit Precedent And Supports Maintaining Declaratory Judgment Jurisdiction In This Case

Contrary to Genzyme’s assertion, (Pl.’s Br. at 9–14), the Federal Circuit’s analysis in *Janssen* is in accord with *Caraco* and supports jurisdiction where, as is the case here, the subsequent-applicant has the potential to enter the market first and did not destroy jurisdiction. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360–61 (Fed. Cir. 2008). The court in *Janssen* agreed with *Caraco* that jurisdiction exists where the subsequent-applicant “could have been blocked from entering the market by an invalid patent.” *Id.* at 1361. The court noted that “[w]ithout a declaratory judgment, Caraco could be excluded from selling a noninfringing product even if the asserted patent was proven to be invalid.” *Id.* The same potential to be blocked by an invalid patent exists here.

In *Janssen*, the first applicant, Teva, filed a paragraph III certification on the earliest-expiring patent, the ’663 patent, and filed paragraph IV certifications on two other patents. *Id.* at 1358. The brand manufacturer did not sue Teva. *Id.* A subsequent-applicant, Apotex, filed paragraph IV certifications on all three patents, but the brand manufacturer only sued Apotex on the ’663 patent. *Id.* The brand manufacturer then granted Apotex a CNS on the two other patents and successfully moved to dismiss Apotex’s counterclaim counts regarding the two other patents. *Id.* at 1358–59.

Because Teva filed a paragraph III certification on the ’663 patent, it had to wait until the ’663 patent’s expiration date before it could enter the market. *Id.*; see also § 355(j)(2)(A)(vii)(III); sec. III.A., *supra*. Apotex did not file any paragraph III certifications and thus had the potential to enter the market before Teva if it maintained its declaratory judgment counts and forced a forfeiture of Teva’s 180-day

exclusivity. *Id.* Stated differently, Apotex could have been “excluded from selling a noninfringing product by an invalid patent” if the court dismissed its counterclaim on the ’663 patent. *Id.* at 1361. Had those been the only facts, the Federal Circuit would have applied *Caraco* and reversed the dismissal. *Id.* at 1360. Unlike *Caraco* and this case, however, Apotex destroyed its potential to enter the market before the first applicant, Teva, when it stipulated to the validity, enforceability, and infringement of the ’663 patent. *Id.* In essence, Apotex destroyed its own declaratory judgment jurisdiction. The Federal Circuit chose not to apply *Caraco* only because of the subsequent-applicant’s action:

We agree with the parties that **if Apotex had not stipulated to the validity of the ’663 patent, then *Caraco* would have been controlling.** However, Apotex stipulated to the validity, infringement, and enforceability of the ’663 patent Therefore, while the harm that created a justiciable Article III controversy in *Caraco* was present when Apotex filed its counterclaims . . . that harm ceased to exist upon Apotex’s stipulation.

Id. (emphasis added). Apotex’s declaratory judgment counts were consequently impotent, because even if Apotex won on the two patents on which it filed declaratory judgment counts, the ’663 patent was still blocking FDA approval. *Id.* at 1361.

Hence, the *Janssen* case accords with *Caraco*, and teaches that, where a subsequent-applicant has the potential to enter the market first, declaratory judgment jurisdiction exists despite the brand manufacturer’s attempts to avoid litigation. Contrary to Apotex, Sandoz has done nothing here to destroy its own standing. *See Janssen*, 540 F.3d at 1360. Rather, Sandoz has the potential to enter the market before Endo if Sandoz wins its case against the ’775 patent and Endo loses or settles. On the other hand, if Sandoz is unable to maintain its counterclaim counts on the ’780 patent, it could be

“blocked from entering the market by an invalid [’775] patent.” *See id.* at 1361. Genzyme should not be allowed to cut-off this potential by purposefully avoiding contest on the ’780 patent.¹³

3. Sandoz’s Loss Of Ability To Challenge The ’780 And Potential To Be The First To Enter The Market Is Injury-In-Fact

Dey, L.P. v. Sepracor, Inc., demonstrates that jurisdiction exists over a subsequent-applicant’s declaratory judgment claim when a subsequent-applicant has the potential to enter the market before the first applicant. 595 F. Supp. 2d 355, 362 (D. Del. 2009) (denying motion to dismiss because “the [subsequent-applicant] could also potentially go to market well in advance of . . . the earliest date that [the first applicant] could go to market”). In *Dey*, the brand manufacturer sued the first applicant, Breath, on all six Orange Book-listed patents. *Id.* at 358. Breath settled with the brand manufacturer and agreed to delay its launch until August 2012. *Id.* The second applicant, Dey, filed paragraph IV certifications on all six patents, but the brand manufacturer only asserted five of the patents. *Id.* at 358–59. Two of the five asserted patents expired after August 2012. *Id.* at 359. Dey filed a declaratory judgment count on the sixth patent, and the brand manufacturer moved to dismiss after granting Dey a CNS on the sixth patent. *Id.*

The court denied the motion to dismiss. The court reasoned that the potential for Dey to enter the market before Breath was enough to grant it declaratory judgment jurisdiction over the sixth patent. *Id.* at 362. The court supported its position by relying on a purpose of the Hatch-Waxman Act to put generic drugs on the market as quickly as possible. *Id.* On motion for certification for interlocutory

¹³ Endo’s argument that *Caraco* is inapplicable because it involved the pre-MMA Hatch-Waxman Act rings hollow. (Ex. 4 at 9). The Federal Circuit explicitly determined that the basis for its decision applied to both pre- and post-MMA (2003) scenarios. *Caraco*, 527 F.3d at 1285 n.4. Further, *Janssen* like *Caraco*, also involved the pre-MMA Hatch-Waxman Act because the first applicant filed its ANDA in 2002. 540 F.3d at 1357 n.2. If *Caraco* is inapplicable, so is *Janssen*.

appeal, the *Dey* court emphasized that because Dey had the potential to enter the market first, declaratory judgment jurisdiction existed. *See Dey L.P. v. Sepracor Inc.*, No. 08-372-JJF, 2009 WL 1043892, at *1 (D. Del. Apr. 16, 2009) (“granting declaratory judgment jurisdiction will . . . allow Dey to possibly go to market earlier”). Moreover, the court found that the declaratory judgment action should go forward—even though it will cause Breath to lose its 180-day exclusivity—because doing so promoted the policies of the Hatch-Waxman Act. *Id.* at *2 n.2 (“[W]hen . . . the brand drug company . . . choose[s] not to sue . . . [the first applicant] so as to delay a final court decision that could trigger the ‘failure to market’ provision [subsequent] applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book”) (citing 149 Cong. Rec. S15885) (statement of Sen. Kennedy).

Sandoz’s situation is analogous to the facts in *Dey*. The ability to challenge the ’780 patent provides Sandoz with the potential to enter the market before Endo because Sandoz could win on that patent while Endo could lose or settle and/or agree to stay off the market for a certain period of time. This threat alone warrants a finding of jurisdiction. Sandoz’s opportunity to bring its drug to market before Endo should not be foreclosed merely because Genzyme unilaterally granted Sandoz a CNS, especially when a central purpose of the Hatch-Waxman statute is to allow generic pharmaceuticals to challenge Orange Book-listed patents in order to bring generic drugs to the market sooner.

4. Genzyme Improperly Focuses On Outcomes, Not Injury

Genzyme’s—and Endo’s—attempt to prevent litigation on the ’780 patent spotlights the controversy. Genzyme incorrectly focuses on possible outcomes to the several litigations in this Court, (Pl.’s Br. at 11–16), but that is not the harm. Sandoz’s harm is that its current potential to enter the market before Endo will be denied if Genzyme is able to flee from judgment against the ’780 patent—a

patent that Genzyme first put at issue. This harm is not dependent on any litigation result, and Sandoz must act now to prevent it. *See Clinton v. City of N.Y.*, 524 U.S. 417, 431 (1998) (“Even if the outcome of the second trial is speculative, the reversal . . . causes a significant immediate injury by depriving the defendant of the benefit of a favorable final judgment.”); *Caraco*, 527 F.3d at 1296 n.14 (“A plaintiff need not prove it will prevail on the merits of its case in order to prove that it has standing to bring the case.”).

Genzyme’s argument that Sandoz’s paragraph III certifications with respect to the 2013 patents somehow remove jurisdiction simply does not make sense. (Pl.’s Br. at 11, 16). Because both the ’775 and the ’780 patents expire after 2013, Sandoz’s potential to enter the market before Endo still exists.¹⁴ Further, if the court engages in evaluating Genzyme’s chart of hypothetical outcomes, (see Pl.’s Br. at 12), then the Court should consider the two most significant results ignored by Genzyme: Endo will (1) lose or (2) settle its challenge against the ’775 patent, while Sandoz will prevail. Should either of these occur and the Court dismisses Sandoz’s Counts III and IV, Genzyme will have successfully protected a two-competitor market and stuck Sandoz with no choice but to wait until Endo markets its drug, regardless of the status of the ’780 and ’775 patents.

5. Endo’s Arguments Do Not Add Anything

Sandoz disagrees that Endo has a protectable interest that warrants intervention. Nonetheless, Endo says nothing more than Genzyme in its memorandum in support, except that Endo also argues that there are a number of ways that it could forfeit its exclusivity period, and thus Sandoz’s injury is speculative. (Ex. 4 at 9). Endo’s argument is a red herring; again, these are outcomes, not harm as the

¹⁴ Moreover, the Hatch-Waxman statute does not require an ANDA applicant to challenge all patents listed in the Orange Book. That Sandoz chose not to challenge the 2013 patents here does not preclude Sandoz from entering the market immediately after their expiration.

case law defines it. *See Clinton*, 524 U.S. at 431; *Caraco*, 527 F.3d at 1296 n.14 . Further, as discussed throughout this brief, only Sandoz can trigger a Failure to Market event, and that ability will be foreclosed if Sandoz is not able to maintain its declaratory judgment counts.

In addition, Endo is not likely to incur any of the other statutory forfeiture events as they would torpedo Endo's own exclusivity. Endo will thus most likely not (1) withdraw its ANDA application, § 355(j)(5)(D)(i)(II); or (2) amend or withdraw its paragraph IV certification on the '780 patent, § 355(j)(5)(D)(i)(III), because Endo has a clear interest in this drug as evidenced by its motion to intervene in two cases to maintain its exclusivity period. Tentative approval is left up to the FDA, and there has been no indication that Endo has manufacturing or similar problems that would cause it to fail to obtain tentative approval. *See* § 355(j)(5)(D)(i)(IV). It similarly makes little sense for Endo to enter into an agreement in violation of antitrust laws that would cause Endo to lose its 180-day exclusivity, and Endo would not lose the exclusivity period that it is fighting for by waiting to market until after the '780 patent expires in 2020. *See* §§ 355(j)(5)(D)(i)(V), (VI).

The only forfeiture event that is of relevance here is the failure to market provision, which only Sandoz can trigger through litigation. Hence, denial of the opportunity to enter the market causes a real and concrete harm to Sandoz, because Sandoz will be restrained by a patent that it does not infringe.

B. This Court Should Exercise Its Discretion To Hear Sandoz's Declaratory Judgment Counterclaims Because Doing So Serves Hatch-Waxman Policies And Promotes Equitable Considerations

Equity favors Sandoz because it has acted in the spirit of the Hatch-Waxman statute, while Genzyme and Endo have acted to stifle competition. Notably, Sandoz did not put itself on the same footing as the first generic applicant in *Janssen*, and thus did not destroy its own jurisdiction. 540 F.3d at 1360.

Endo first filed a paragraph IV challenge only against the '780 patent. Endo thus elected to wait until the '775 patent expired on September 16, 2014 to launch its sevelamer product. It was only after Sandoz had challenged the '775 patent that Endo converted its paragraph III certification on the '775 patent to a paragraph IV certification. Moreover, Endo has affirmatively acted to keep the '780 patent out of litigation in an effort to maintain its exclusivity. When Impax declined to withdraw its declaratory judgment counterclaim counts related to the '780 patent, Genzyme moved to dismiss. (*See* Ex. 10). Endo then moved to intervene in support of the motion to dismiss, arguing that its exclusivity period was a right to which it was entitled. (*See* Ex. 15, Endo Mot. Intervene, Dkt. No. 51, at 4–6). Endo filed a nearly identical motion in this case. (Ex. 4 at 3, 10–11). Therefore, Endo, like Genzyme, has attempted to ensure that, once it is able to market, Endo and Genzyme are the only competitors. Such a strategy not only causes potential lost profits to Sandoz, but also harms the public from benefitting from competition in the marketplace.

One district court has discussed the role that a court plays should it allow a brand manufacturer to control the generic market by granting a CNS and then moving to dismiss a declaratory judgment count. *See Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 424–26 (D. Del. 2007), *aff'd in part, vacated in part as moot*, 287 F. Appx. 884 (Fed. Cir. 2008). Although the court rendered its decision a year before the Federal Circuit's analysis in *Caraco* and *Janssen*, the court's discussion of the "Manipulation of Court Jurisdiction" is still on point:

Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. **In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible.**

Id. at 424 (emphasis added).

The *Dey* court further commented that the harm a first applicant causes if it extends its exclusivity period by delaying market entry is contrary to Hatch-Waxman policy. *See Dey*, 2009 WL 1043892, at *2 (“allowing [the first applicant] to initiate a challenge to a pharmaceutical patent, give up that challenge, and then pocket the 180-day exclusivity period for an extended period-to the detriment of all other generic manufacturers-does not . . . vindicate the policy goal underlying the 180-day exclusivity period.”). The *Dey* court recognized that the MMA, which gives generic defendants a clear right to assert a declaratory judgment claim against an unasserted Orange Book-listed patent, was “designed to prevent” a first applicant from “block[ing] all other generics from entering the market” in such a manner. *Id.* (citing 149 Cong. Rec. S16105 (Dec. 9, 2003)).

The Hatch-Waxman Act is designed to foster competition, not deter it. Sandoz is trying to bring a generic sevelamer hydrochloride tablet to market as quickly as possible, while Genzyme and Endo are acting to suppress competition. The court’s statements in *Merck* distinctly point out the harm caused if a court permits the brand manufacturer to control competition. When all the circumstances are considered, a CNS does more harm than good when the subsequent-applicant has the potential to enter the market before the first applicant. Thus, because of the harm Genzyme’s actions are causing Sandoz, other subsequent-applicants, and the public as a whole, this Court should exercise its discretion to hear Sandoz’s declaratory judgment claims.

V. CONCLUSION

Genzyme's actions directly contradict the balance Congress struck between rewarding the research and development of new drugs and encouraging competitors to bring low-cost, generic drugs to market. Permitting Sandoz to maintain its declaratory judgment counts is the only way to ensure that a generic Renagel[®] product reaches the public as soon as possible. For the foregoing reasons, Genzyme's motion to dismiss Sandoz's declaratory judgment claims should be denied.

Respectfully submitted,

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